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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,662	11/24/2003	Hong-Mo Moon	038779/271509	6451

826 7590 06/27/2005

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/720,662

Applicant(s)

MOON ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 13 and 19-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-12 and 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5-12-05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Currently, claims 1-43 are pending in the application. In the prior action, mailed on January 11, 2005, claims 6-12, and 14-18 were rejected, and claims 1-5, 13, and 19-43 were withdrawn as to non-elected inventions. In the Response of April 12, 2005, the Applicant amended claims 9-12, and 14-18.
2. Claims 6-12 and 14-18 are under consideration.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on May 12, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Claim Objections

4. **(New Objection)** Claims 9 and 16 are objected to because of the following informalities: the use of the term “or” with respect to amino acid positions 15 and 123 is redundant to, or conflicts with, the “one or both” describing the asparagine residues at these positions. It is suggested that the claim be amended to read one nucleic acid sequences wherein the gene codes for a mutant pre-S - - in which one or both asparagine of a wild-type pre-S at amino acid positions 15 and 123 are replaced- - . Appropriate correction is required.

Claim Rejections - 35 USC § 101 and 112

5. 35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. **(New Rejection- Necessitated by Amendment)** Claims 14-18 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either an operable asserted utility or a well established utility. Claim 9 reads on a recombinant vector encoding a modified pre-S protein. The claim is silent regarding the present of any addition sequences other than the pre-S mutant, and is therefore read as open, and including embodiments comprising additional sequences to the pre-S coding sequence. Claim 14 (and dependent claims 15-18) are describe yeast cells transformed with the vectors “wherein the transformant secretes the mutant pre-S into culture media.” The Applicant asserts on page 9 of the Response, that transformants encoding the full length of the L protein (i.e. the pre-S and S proteins) was not capable of secreting the protein into the culture media. The Applicant asserts that only vectors encoding only the modified pre-S proteins (i.e. not linked to the S protein) are capable of secretion. In view of this assertion by the Applicant, and because the claims do not exclude the embodiments asserted to be inoperable, the claims are rejected as reading on inoperable subject matter.

Claim Rejections - 35 USC § 101 and 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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8. **(New Rejection- Necessitated by Amendment)** Claims 14-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for yeast transformants comprising nucleic acids encoding the double mutant pre-S protein, comprising only the pre-S region the L protein wherein the proteins are secreted into the culture media, does not reasonably provide enablement for any transformant comprising a vector encoding any pre-S encoding nucleic acid according to claim 9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. Claim 9 reads on a recombinant vector encoding a modified pre-S protein. The claim is silent regarding the present of any addition sequences other than the pre-S mutant, and is therefore read as open, and including embodiments comprising additional sequences to the pre-S coding sequence. Claim 14 (and dependent claims 15-18) are describe yeast cells transformed with the vectors “wherein the transformant secretes the mutant pre-S into culture media.”

The Applicant asserts on page 9 of the Response, that transformants encoding the full length of the L protein (i.e. the pre-S and S proteins) was not capable of secreting the protein into the culture media. Because the claims read on embodiments wherein additional sequence to the pre-S sequence are encoded by the vector, and because the Applicant has asserted that such embodiments are not operable, the Applicant has not provided sufficient information to enable the full scope of the claimed inventions.

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9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. **(Prior Rejection- Maintained)** Claims 6-12 and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Kniskern et al. (U.S. Patent 5,614,384) in view of Takahashi et al. (Arch Virol 143: 2313-26) and of Essex (U.S. Patent 6103, 238) and O.Narhi et al. (Protein Engineering 14: 135-40). The Applicant traverses this rejection on the grounds that the cited references do not teach the expression of modified pre-S proteins with linkage to the S-protein. It is first noted that the claims are not directed to methods of expression, but to nucleic acids encoding the mutant pre-S protein. Second, it is noted that the claims nowhere require that the claimed nucleic acids encode the modified pre-S proteins without linkage to the S protein. Thus, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Because the Applicant's arguments are based upon limitations that are not found within the claims, the rejection is maintained.

The Applicant additionally argues unexpected results with respect to the claimed compositions. In particular, the Applicant asserts that the modified pre-S sequences without linkage to the S protein achieve unexpected results. However, as indicated above, even if it were assumed that such pre-S sequences did achieve such unexpected results, because the present

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claims do not require that the pre-S proteins are not linked to the S protein, such showings would not be commensurate in scope with the inventions being claimed. The argument is therefore not found persuasive. The rejection is therefore maintained.

11. **(Prior Rejection- Maintained)** Claims 6-12 and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Comberbach et al. (U.S. Patent 6,103,519) in view of Takahashi and Essex. The claims have been described above. The Applicant traverses this rejection for substantially the same reasons as indicated above, and on the basis that the Comberbach reference fails to teach the secretion of a protein from the transformed cells.

The first argument, that the references fail to teach the lack of a linkage between the mutated pre-S protein and the S protein, and the assertion of unexpected results, are not found persuasive for the reasons indicated above. The Applicant has nowhere provided a claim limitation requiring that there is no linkage between the encoded pre-S protein and an S-protein sequence.

The Applicant next asserts that the Comberbach reference fails to teach the secretion of proteins from the transformed cells. However, the claims are not directed to methods of secreting proteins from cells. Nor do claims 6-12 require the secretion of nucleic acids from the cells. The arguments in traversal are therefore not found persuasive with respect to claims 6-12.

With respect to claims 14-18, it is noted that the Applicant has provided no demonstration that the claimed nucleic acids differ structurally from those that would result from the cited combination of references. While the Applicant asserts that the claims read on only the pre-S domain not linked to the S protein (thus not reading on the L protein), there is no basis for

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finding this limitation in the claims. Because there is no structural distinction between the claimed inventions and those suggested by the prior art, the teachings of the reference would result in the making of a nucleic acid with the same functional attributes as the claimed inventions.

Further, the Applicant's arguments with respect to the enablement of the Comberbach reference for the secretion of the L protein is mere argument by the Applicant. They have provided no evidence (e.g., in the form of a declaration) in support of the assertion. As indicated by MPEP 2144, "The arguments of counsel cannot take the place of evidence in the record." Because the Applicant is making a factual assertion, support for this assertion is required to overcome the prima facie case made by the Examiner. As the Applicant has not presented such evidence, the assertion is not found persuasive to overcome the rejection. In addition, the teachings of Comberbach are not limited to the production of the L protein, but include the production of any of the S proteins, including the pre-S protein. It would therefore have been obvious from the teachings of the cited references for those in the art to produce a modified version of the pre-S protein. The failure of the L protein to be secreted would not necessarily demonstrate that the reference is not enabling for the pre-s variants because the art recognizes that the L protein is averse to secretion. See e.g., Chisari et al., J Virol 60: 880-87 (of record in the May 2005 IDS). Thus, even if the Applicant's assertions regarding the expression of the L protein were supported, such would not be sufficient to overcome the rejection based on embodiments wherein only the pre-S protein is included in the expression vector.

For these reasons, and the reasons of record, the rejection is maintained.

Conclusion

12. No claims are allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

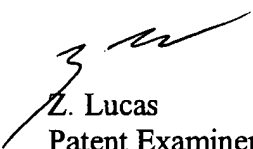
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas
Patent Examiner



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